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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,009	12/22/1999	JEONG S. LEE	003764.P006	5656

7590 11/05/2003

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/470,009

Applicant(s)

LEE ET AL.

Examiner

Ann Y. Lam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-26 and 39-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-26 and 39-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

In view of the appeal brief filed on March 5, 2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 112

Claims 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11, in the preamble, indicates that Applicant is claiming a catheter; however, in the body of the claim, Applicant does not positively claim a catheter, but rather only claims a mandrel. Thus, it is unclear whether or not Applicant is claiming a catheter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 11, 13-18, 19, 21-26, 39-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Evard, 5,242,396.

As to claim 11, Evard discloses a mandrel (26) comprised of a variable stiffness, non-metal material (see column 3, lines 38-42, and column 4, lines 28-30) said mandrel uniformly tapered from a proximal section to a distal section (see column 3, lines 38-42, and Figure 1), and said mandrel adapted to reinforce a catheter (see Figure 1.)

As to claim 19, Evard discloses an outer member (17); a hollow inner member (14) extending through said outer member; an outer lumen (18) between said inner and outer members; and a mandrel extending through said outer lumen, said mandrel comprised of a variable stiffness material, said mandrel uniformly tapered, see column 3, lines 38-42, from a proximal section to a distal section and said mandrel is adapted to reinforce said catheter (see Figure 1.)

As to claims 13, 21, 44, 50 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, see Figure 1.

As to claims 14, 22, 40, 46 and 52, the catheter comprises an inflatable member (12, 22 and 23) comprising a proximal portion (i.e., proximal portion of 23) and a distal portion (i.e., portion of balloon that includes distal portion of 23), wherein said distal

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section of said mandrel (26) extends past said proximal portion of said inflatable member, see Figure 1. (Applicant has not defined in the claims where the proximal portion and distal portion of the inflatable member begins and ends.)

As to claims 15, 23, 41, 47 and 53, said distal section of said mandrel (26) extends past said distal portion (i.e., portion of balloon that includes distal portion of 23) of said inflatable member, see Figure 1.

As to claims 16, 24, 42, 45, 48 and 55, said mandrel (26) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claims 17, 25, 39 and 54, said mandrel (26) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 26, 43, 49 and 51 said mandrel (26) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

As to claims 57, 59, 61, 63 and 65, the mandrel is fixed to the catheter shaft (see column 3, lines 38-39.)

As to claims 58, 60, 62, 64, and 66 an inner tubular member (14) is disposed near the mandrel, wherein the inner tubular member is adapted to receive a guidewire (see column 3, lines 21-26.)

2. Claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Shank et al., 5,147,317. Shank et al. discloses a mandrel (10) comprised of a variable stiffness, non-metal material, see column 7, line 5, said mandrel uniformly tapered (34) from a proximal section to a distal section, and said mandrel adapted to reinforce a catheter.

As to claims 13, 44, 50 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, see Figure 2.

As to claims 16, 42, 45, 48 and 55, said mandrel (10) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claims 17, 39 and 54, said mandrel (10) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 43, 49 and 51 said mandrel (10) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

3. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Hibbs et al., 4,950,257. Hibbs et al. discloses a mandrel (20), comprised of a variable stiffness, non-metal material, said mandrel uniformly tapered from a proximal section to a distal section, and said mandrel adapted to reinforce said catheter. The material is polyamide, see column 2, line 16.

Claim Rejections - 35 USC § 103

4. Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard, 5,242,396, in view of Maguire et al., 6,599,288.

Evard discloses the invention substantially as claimed, see above, except for the material being specifically polyimide. Evard does however teach that the reinforcing mandrel can be of high strength plastic, see column 4, lines 28-31.

Maguire et al. discloses a catheter with a mandrel made of polyimide material (see column 58, lines 35-40.) Maguire et al. also discloses that polyimide is a rigid material (see column 53, lines 24-28.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Evard mandrel from a high strength plastic, as suggested by Evard, such as polyimide, as taught by Maguire et al. as a known rigid material used to form mandrels.

Response to Arguments

Applicant's arguments filed March 5, 2003 have been fully considered but they are not persuasive.

Applicant argues that Shank discloses a guidewire that is made of steel, see page 5 of Applicant's brief. In response, Examiner points out that the Shank guidewire is coated with polytetrafluoroethylene (see column 7, lines 2-5.)

Applicant also argues that a mandrel is not equivalent to a guidewire, see page 6 of Applicant's brief. In response, Examiner reasserts that a mandrel and guidewire are equivalent to the extent that they are the same product, i.e., they have the same structure and are used to reinforce a catheter.

Applicant also argues that new claims 57, 61, 63 and 65 include the limitation of the mandrel fixed to the catheter, see page 6 of Applicant's brief. In response, Examiner points out that these newly added claims in the brief will not be entered and thus will not be considered.

Applicant also argues that the claimed mandrel is formed from the various procedures claimed by Applicant. In response, Examiner points out that Applicant is claiming a product, as opposed to a method of making. Thus, the claims are anticipated if the product is found in the prior art. As described in the above rejection, the product as claimed by Applicant is found in the prior art.

Applicant also argues that Hibbs does not disclose a mandrel that is fixed to a catheter, and that newly added claim 57 includes this limitation, see page 8 of Applicant's brief. In response, Examiner points out that the newly added claims reciting a fixed mandrel is rejected above under Evard.

Applicant's arguments with respect to the rejections under Kraus in view of Lorenzo, see page 8-10 of Applicant's brief, have been considered but are moot in view of the new ground(s) of rejection (see the above rejections under Evard.)


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L. 


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641